K002410

1/4

JUN - 6 2001

510(k) Summary
as Required by 21 C.F .R. 807.92

1. **Submitter Information**
   Marcy Freed Co-Manager
   Dysphagia, L.L.C.
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   Date: August 4, 2000

2. **Device Identification**
   Freed Bioelectric: Dysphagia Treatment Device

3. **Legally Marketed**
   (Predicate) Device Staodyn@ EMS+2 (K926510)

4. **Description of the Device**
   The Freed Bioelectric: Dysphagia Treatment Device is a two-channel portable pulse generator for external electrical neuromuscular stimulation. It delivers 1/4 of the current of typical general purpose powered muscle stimulators. Accessories are electrodes, electrode leads, and snap connectors.

5. **Intended Use of the Device**
   The Freed Bioelectric: Dysphagia Treatment Device is an external electrical stimulation device intended for muscle re-education in the throat muscles necessary for pharyngeal contraction, to allow swallowing of food without aspiration. It is indicated for treatment of dysphagia (swallowing problems) from any etiology except mechanical causes that would need surgical intervention (for instance, obstructing tumors). Non- mechanical causes of dysphagia include: neurological and muscle disorders; cardiovascular accidents; respiratory disorders with swallowing complications; iatrogenic conditions (conditions caused by surgery); radiation stenosis to the pharynx arising from radiation therapy; non-use due to stroke, intubation, or birth- related anoxic injuries; and trauma to the head and neck. This device is a prescription device intended for use by or on the order of a physician or other licensed health professional.

6. **Summary Compared to Predicate Product Technological Characteristics**
   Electrical stimulation is traditionally used in large muscle groups in the back, on the arms, and on the legs. It has not traditionally been used in the neck area.
   The Freed Bioelectric: Dysphagia Treatment Device and the predicate Staodyn®

Substantial Equivalency Comparison

The Freed Bioelectric: Dysphagia Treatment Device has the same basic intended use as the Staodyn@ EMS+2: it is intended for muscle re-education in the throat muscles necessary for pharyngeal contraction, to allow swallowing of food without aspiration. However, the Freed Bioelectric: Dysphagia Treatment Device is indicated for external application to the throat and stimulation of the muscles necessary for pharyngeal contractions in the treatment of dysphagia (swallowing problems).

The Freed Bioelectric device has the same primary technological characteristics as the Staodyn@ EMS+2: it is made of the same materials, it is built according to the same design, and it uses the same energy source. The device's electrodes are smaller, and both voltage and current are lower. Four features that were adjustable on the predicate device -pulse rate, pulse width, mode (AC or DC), and operation of channels (simultaneous or sequential) -are fixed on the modified device. Also, the predicate device offered a choice between constant stimulation and stimulation cycles (with ramping up time, on time, ramping down time, and off time); the modified device uses only constant stimulation.

Our performance data show that the differences between the Freed Bioelectric device and the Staodyn device do not raise new questions of safety and effectiveness. The changes to the EMS+2 device are specifically intended to allow use of the Freed Bioelectric: Dysphagia Treatment Device on the throat muscles necessary for pharyngeal contraction, where the Staodyn@ EMS+2 is not intended for use.

The manufacturer of the Freed Bioelectric: Dysphagia Treatment Device is Rehabilicare, Inc., which acquired the product lines and intellectual property of Staodyn,

Clinical Study Results

I. INTRODUCTION

- One clinical study was performed, involving a total of 892 patients from 1993 to 1998.
- The purpose of the study was to support the intended use for muscle re-education in the throat muscles necessary for pharyngeal contraction, to allow swallowing of food without aspiration.
- From the start of the study until July 1995' 167 patients were assigned randomly to either thermal application (TA, n=58 patients) or electrical stimulation (ES1, n=109 patients). The vast majority of these patients suffered from dysphagia caused by cerebral vascular accident (CVA patients) (n=99) or dysphagia caused by neurodegenerative disease (NDG patients) (n=43). As shown in **Table 1**, these two treatment groups were similar in demography, health conditions, and distribution of initial swallow function.
- Beginning in June 1995, a different type of electrical simulation (ES2) was applied that used different electrode placement and current. The primary difference between ES1 and ES2 was that ES2 caused an involuntary swallow. This enabled a patient to swallow when the ES1 stimulation failed. (One patient who was initially randomized to ES1 and who did not improve at all was given ES2, and has been analyzed as an ES2 patient.) Preliminary analysis at this time showed overwhelming superiority of electrical stimulation over thermal application, and the hospitalIRB enabled physicians to assign patients directly to ES2.
- The randomized portion of the study ended at this point. ES2 was applied to enough patients to obtain a sample size of 30 patients that started at swallow function 0/1 and achieved swallow function 6 after treatment. This was done so that a comparison could be made with ES1 on the number of treatments required for success. This involved 175 ES2 patients up to July 1996. An additional 550 ES2 patients through 1998 completed the study.

	TA	ES1	ES2		
1993 to July 1, 1995	58	109			
July 2, 1995- July 1996			175	12 with ≤ 2 treatments	
				12 with > 2 treatments	
July 1996- 1998			550	22 with ≤ 2 treatments	
				528 with > 2 treatments	
Total	**58**	**109**	**725**		**892**

INFORMATION FOR PRESCRIBERS

Caution: ***This is a prescription device intended for use by or on the order of a physician or other licensed health professional.***

1. ***BRIEF DEVICE DESCRIPTION***

The Freed Bioelectric: Dysphagia Treatment Device is a two channel, portable pulse generator for external electrical neuro-muscular stimulation. It provides continuous stimulation. Each stimulation channel serves two electrodes. The system includes electrodes, lead wires, and a 9-volt alkaline battery. This device delivers ¼ of the current of general purpose muscle stimulators.

2. ***INTENDED USE/INDICATIONS***

The Freed Bioelectric: Dysphagia Treatment Device is intended for muscle re-education in the throat muscles necessary for pharyngeal contraction. The device is indicated for treatment of dysphagia from any etiology other than mechanical causes requiring surgery.

3. ***CONTRAINDICATIONS***

This device should be used with caution on patients with cardiac demand pacemakers.

4. ***WARNINGS***

- The long term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- If electrodes are placed improperly and the unit is not used with the recommended frequency, intensity, and pulse, it may cause laryngeal or pharyngeal spasm. Severe spasm of the laryngeal and pharyngeal muscles can close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically because the introduction of electrical current into the heart may cause cardiac arrhythmias.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Ms. Marcy Freed, ST
Co-Manager
Dysphagia, L.L.C.
3011 Kersdale Road
Cleveland, Ohio 44124

Re: K002410
Trade Name: Freed Bioelectric: Dysphagia Treatment Device
Regulation Number: 890.5850
Regulatory Class: II
Product Code: IPG
Dated: April 13, 2001
Received: April 16, 2001

Dear Ms. Freed:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K00 2410

Device Name: Freed Bioelectric: Dysphagia Treatment Device

Indications For Use:

Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K002410